

FILED
CLERK, U.S. DISTRICT COURT

JUL 6 2011

CENTRAL DISTRICT OF CALIFORNIA
EASTERN DIVISION BY DEPUTY

Attorneys for Plaintiffs
SHIRE LLC and SHIRE DEVELOPMENT INC.

EASTERN DIVISION

CV 11 Case No. 05588

COMPLAINT FOR PATENT INFRINGEMENT

WATSON LABORATORIES, INC.,

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

1 Plaintiffs Shire LLC and Shire Development Inc. (collectively "Shire"), by
 2 their undersigned attorneys, for their Complaint against defendant Watson
 3 Laboratories, Inc. ("Watson") herein, allege as follows:

4 **JURISDICTION AND VENUE**

5 1. This Court has jurisdiction over the subject matter of this action pursuant
 6 to 28 U.S.C. §§ 1331 and 1338(a).

7 2. This Court has personal jurisdiction over Watson. Watson has submitted
 8 to personal jurisdiction in this Court because, *inter alia*, it resides, and is doing
 9 business in this District.

10 3. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and
 11 (c), and § 1400(b).

12 **NATURE OF THE ACTION**

13 4. This is an action for patent infringement arising under the patent laws of
 14 the United States, Title 35, United States Code, involving United States Patent No.
 15 7,105,486 ("the '486 patent") (attached as Exhibit A hereto); United States Patent No.
 16 7,223,735 ("the '735 patent") (attached as Exhibit B hereto); and United States Patent
 17 No. 7,700,561 ("the '561 patent") (attached as Exhibit C hereto).

18 **THE PARTIES**

19 5. Plaintiff Shire LLC is a corporation organized and existing under the
 20 laws of the State of Kentucky, having a place of business at 9200 Brookfield Court,
 21 Florence, Kentucky 41042.

22 6. Plaintiff Shire Development Inc. is a corporation organized and existing
 23 under the laws of the State of Delaware, having a place of business at 725
 24 Chesterbrook Boulevard, Wayne, Pennsylvania 19087.

25 7. Upon information and belief, Watson Laboratories, Inc. is a corporation
 26 organized and existing under the laws of the State of Nevada, having its principal
 27 place of business in this District at 311 Bonnie Circle, Corona, California 92880.
 28

FACTS AS TO ALL COUNTS

8. Shire Development Inc. is the owner of New Drug Application (“NDA”) No. 021977, which was approved by the FDA for the manufacture and sale of Vyvanse®. Vyvanse® is the trade name for lisdexamfetamine dimesylate, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg capsules for oral administration and is approved for the treatment of Attention Deficit Hyperactivity Disorder (“ADHD”).

9. Pursuant to 21 U.S.C. § 355(b)(1), the ’486 patent, the ’735 patent, and the ’561 patent (“the Patents-in-Suit”) are listed in FDA’s publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “*Orange Book*”) as covering the Vyvanse® product.

10. Shire LLC has been assigned, and currently owns, the rights to each of the Patents-in-Suit.

11. The ’486 patent, titled “Abuse-Resistant Amphetamine Compounds,” was duly and legally issued on September 12, 2006. The ’486 patent is generally directed to methods of treatment using L-lysine-d-amphetamine

12. The ’735 patent, titled “Abuse Resistant Lysine Amphetamine Compounds,” was duly and legally issued on May 29, 2007. The ’735 patent is generally directed to pharmaceutical compositions comprising L-lysine-d-amphetamine.

13. The ’561 patent, titled “Abuse-Resistant Amphetamine Prodrugs” was duly and legally issued on April 20, 2010. The ’561 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

14. Watson prepared, submitted, and filed Abbreviated New Drug Application (“ANDA”) No. 202818 (“the Watson ANDA”) to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic lisdexamfetamine dimesylate capsules, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg, for oral administration (“the Watson Proposed

1 Product”).

2 15. Watson sent a letter to Shire LLC, Shire Development Inc., Shire
3 Pharmaceuticals Inc., and Shire US Inc. purporting to provide notification that the
4 Watson ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a
5 “paragraph IV certification”) with regard to the ’486 patent, the ’735 patent, and the
6 ’561 patent (“the Watson Notice Letter”).

7 16. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent
8 holder of the filing of an ANDA containing a paragraph IV certification “include a
9 detailed statement of the factual and legal basis of the opinion of the applicant that the
10 patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(6)
11 requires a paragraph IV notification to include “[a] detailed statement of the factual
12 and legal basis of applicant’s opinion that the patent is not valid, unenforceable, or
13 will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a
14 patent alleged not to be infringed, a full and detailed explanation of why the claim is
15 not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or
16 unenforceable, a full and detailed explanation of the grounds supporting the
17 allegation.” 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

18 17. The Watson Notice Letter does not assert non-infringement for each and
19 every claim of each and every patent for which Watson has made a paragraph IV
20 certification.

21 18. The Watson Notice Letter does not provide a full and detailed
22 explanation of Watson’s factual and legal basis of invalidity and/or unenforceability
23 for each and every claim of each and every patent for which Watson has made a
24 paragraph IV certification.

25 19. The Watson Notice Letter does not address United States Patent No.
26 7,655,630 (“the ’630 patent”); United States Patent No. 7,659,253 (“the ’253 patent”);
27 U.S. Patent No. 7,659,254 (“the ’254 patent”); United States Patent No. 7,662,787
28 (“the ’787 patent”); United States Patent No. 7,671,030 (“the ’030 patent”); United

1 States Patent No. 7,671,031 (“the ’031 patent”); United States Patent No. 7,674,774
 2 (“the ’774 patent”); United States Patent No. 7,678,770 (“the ’770 patent”); United
 3 States Patent No. 7,678,771 (“the ’771 patent”); United States Patent No. 7,687,466
 4 (“the ’466 patent”); United States Patent No. 7,687,467 (“the ’467 patent”); United
 5 States Patent No. 7,718,619 (“the ’619 patent”); and United States Patent No.
 6 7,723,305 (“the ’305 patent”), each also listed in the Orange Book for Vyvanse®.

7 20. On information and belief, Watson made certifications under 21 U.S.C. §
 8 355(j)(2)(A)(vii)(III) (“a paragraph III certification”) for the ’630 patent, the ’253
 9 patent, the ’254 patent, the ’787 patent, the ’030 patent, the ’031 patent, the ’774
 10 patent, the ’770 patent, the ’771 patent, the ’466 patent, the ’467 patent, the ’619
 11 patent, and the ’305 patent.

12 21. On information and belief, Watson does not seek approval of the Watson
 13 ANDA before the expiration of the ’630 patent, the ’253 patent, the ’254 patent, the
 14 ’787 patent, the ’030 patent, the ’031 patent, the ’774 patent, the ’770 patent, the ’771
 15 patent, the ’466 patent, the ’467 patent, the ’619 patent, and the ’305 patent.

16 22. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), the Watson Notice Letter
 17 contained an Offer of Confidential Access to the Watson ANDA. Shire requested a
 18 copy of the Watson ANDA and samples of the Watson Proposed Product from
 19 Watson. Watson has not produced the Watson ANDA or any samples of Watson
 20 Proposed Product.

21 FIRST COUNT

22 (Infringement of the ’486 Patent by Watson)

23 23. Shire repeats and realleges each of the foregoing paragraphs as if fully
 24 set forth herein.

25 24. Upon information and belief, Watson seeks FDA approval for the
 26 manufacture, marketing, sale, and/or distribution of the Watson Proposed Product.

27 25. Upon information and belief, Watson included a paragraph IV
 28 certification to the ’486 patent to obtain approval to engage in the commercial

1 manufacture, use, sale, offer for sale and/or importation of the Watson Proposed
2 Product before the expiration of the '486 patent.

3 26. Upon information and belief, Watson will commercially manufacture,
4 sell, offer for sale, and/or import the Watson Proposed Product upon FDA approval.

5 27. Upon information and belief, as of the date of the Watson Notice Letter,
6 Watson was aware of the statutory provisions and regulations set forth in 21 U.S.C. §
7 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

8 28. The inclusion of a paragraph IV certification to the '486 patent in ANDA
9 No. 202818 for the purpose of obtaining approval to engage in the commercial
10 manufacture, use, sale, offer for sale and/or importation of the Watson Proposed
11 Product before the expiration of the '486 patent is an act of infringement by Watson
12 of one or more claims of the '486 patent under 35 U.S.C. § 271(e)(2)(A) directly
13 and/or indirectly, including by inducement and/or contributory infringement.

14 29. Upon information and belief, Watson's commercial manufacture, use,
15 sale, offer for sale and/or importation into the United States of the Watson Proposed
16 Product that is the subject of ANDA No. 202818 will infringe one or more claims of
17 the '486 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. §
18 271(c).

19 30. Upon information and belief, Watson is aware of the existence of the
20 '486 patent and acted without a reasonable basis for believing that it would not be
21 liable for infringement of the '486 patent, thus rendering this case "exceptional" under
22 35 U.S.C. § 285.

23 31. The acts of infringement set forth above will cause Shire irreparable
24 harm for which it has no adequate remedy at law, unless Watson is preliminarily and
25 permanently enjoined by this Court.

26 SECOND COUNT

27 (Infringement of the '735 Patent by Watson)

28 32. Shire repeats and realleges each of the foregoing paragraphs as if fully

1 set forth herein.

2 33. Upon information and belief, Watson seeks FDA approval for the
3 manufacture, marketing, sale, and/or distribution of the Watson Proposed Product.

4 34. Upon information and belief, Watson included a paragraph IV
5 certification to the '735 patent to obtain approval to engage in the commercial
6 manufacture, use, sale, offer for sale and/or importation of the Watson Proposed
7 Product before the expiration of the '735 patent.

8 35. Upon information and belief, Watson will commercially manufacture,
9 sell, offer for sale, and/or import the Watson Proposed Product upon FDA approval.

10 36. Upon information and belief, as of the date of the Watson Notice Letter,
11 Watson was aware of the statutory provisions and regulations set forth in 21 U.S.C. §
12 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

13 37. The inclusion of a paragraph IV certification to the '735 patent in ANDA
14 No. 202818 for the purpose of obtaining approval to engage in the commercial
15 manufacture, use, sale, offer for sale and/or importation of the Watson Proposed
16 Product before the expiration of the '735 patent is an act of infringement by Watson
17 of one or more claims of the '735 patent under 35 U.S.C. § 271(e)(2)(A) directly
18 and/or indirectly, including by inducement and/or contributory infringement.

19 38. Upon information and belief, Watson's commercial manufacture, use,
20 sale, offer for sale and/or importation into the United States of the Watson Proposed
21 Product that is the subject of ANDA No. 202818 will infringe one or more claims of
22 the '735 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. §
23 271(c).

24 39. Upon information and belief, Watson is aware of the existence of the
25 '735 patent and acted without a reasonable basis for believing that it would not be
26 liable for infringement of the '735 patent, thus rendering this case "exceptional" under
27 35 U.S.C. § 285.

28 40. The acts of infringement set forth above will cause Shire irreparable

1 harm for which it has no adequate remedy at law, unless Watson is preliminarily and
2 permanently enjoined by this Court.

3 THIRD COUNT

4 **(Infringement of the '561 Patent by Watson)**

5 41. Shire repeats and realleges each of the foregoing paragraphs as if fully
6 set forth herein.

7 42. Upon information and belief, Watson seeks FDA approval for the
8 manufacture, marketing, sale, and/or distribution of the Watson Proposed Product.

9 43. Upon information and belief, Watson included a paragraph IV
10 certification to the '561 patent to obtain approval to engage in the commercial
11 manufacture, use, sale, offer for sale and/or importation of the Watson Proposed
12 Product before the expiration of the '561 patent.

13 44. Upon information and belief, Watson will commercially manufacture,
14 sell, offer for sale, and/or import the Watson Proposed Product upon FDA approval.

15 45. Upon information and belief, as of the date of the Watson Notice Letter,
16 Watson was aware of the statutory provisions and regulations set forth in 21 U.S.C. §
17 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

18 46. The inclusion of a paragraph IV certification to the '561 patent in ANDA
19 No. 202818 for the purpose of obtaining approval to engage in the commercial
20 manufacture, use, sale, offer for sale and/or importation of the Watson Proposed
21 Product before the expiration of the '561 patent is an act of infringement by Watson
22 of one or more claims of the '561 patent under 35 U.S.C. § 271(e)(2)(A) directly
23 and/or indirectly, including by inducement and/or contributory infringement.

24 47. Upon information and belief, Watson's commercial manufacture, use,
25 sale, offer for sale and/or importation into the United States of the Watson Proposed
26 Product that is the subject of ANDA No. 202818 will infringe one or more claims of
27 the '561 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. §
28 271(c).

1 attorneys, and those persons in active concert or participation or privity with them or
2 any of them, from engaging in the commercial manufacture, use, sale, offer to sale
3 and/or importation in the United States of the product that is the subject of ANDA No.
4 202818 until the expiration of the '486 patent including any regulatory extensions;

5 6. A judgment awarding Shire damages or other monetary relief, pursuant
6 to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Watson commercially manufactures, uses,
7 sells, offers to sell and/or imports any product that is the subject of ANDA No.
8 202818 that infringes the '486 patent;

9 7. A judgment declaring that infringement of the '486 patent is willful if
10 Watson commercially manufactures, uses, sells, offers to sell and/or imports any
11 product that is the subject of ANDA No. 202818 that infringes the '486 patent;

12 8. A judgment declaring that the '735 patent is valid and enforceable;

13 9. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the
14 submission to the FDA and filing of ANDA No. 202818 with a paragraph IV
15 certification to obtain approval for the commercial manufacture, use, sale, offer for
16 sale and/or importation in the United States of the product that is the subject of
17 ANDA No. 202818 was an act of infringement of the '735 patent by Watson directly
18 and/or indirectly, including by inducement and/or contributory infringement;

19 10. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. §
20 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for
21 sale and/or importation in the United States of the product that is the subject of
22 ANDA No. 202818 prior to the expiration of the '735 patent, including any regulatory
23 extensions, will constitute an act of infringement by Watson directly and/or indirectly,
24 including by inducement and/or contributory infringement;

25 11. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of
26 any approval of the product that is the subject of ANDA No. 202818 shall be no
27 earlier than the date on which the '735 patent expires including any regulatory
28 extensions;

12. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Watson and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 until the expiration of the '735 patent including any regulatory extensions;

13. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Watson commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202818 that infringes the '735 patent;

14. A judgment declaring that infringement of the '735 patent is willful if Watson commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202818 that infringes the '735 patent;

15. A judgment declaring that the '561 patent is valid and enforceable;

16. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202818 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 was an act of infringement of the '561 patent by Watson directly and/or indirectly, including by inducement and/or contributory infringement;

17. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 prior to the expiration of the '561 patent, including any regulatory extensions, will constitute an act of infringement by Watson directly and/or indirectly, including by inducement and/or contributory infringement;

18. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202818 shall be no

1 earlier than the date on which the '561 patent expires including any regulatory
2 extensions;

3 19. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and
4 permanently enjoining Watson and their officers, agents, servants, employees and
5 attorneys, and those persons in active concert or participation or privity with them or
6 any of them, from engaging in the commercial manufacture, use, sale, offer to sale
7 and/or importation in the United States of the product that is the subject of ANDA No.
8 202818 until the expiration of the '561 patent including any regulatory extensions;

9 20. A judgment awarding Shire damages or other monetary relief, pursuant
10 to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Watson commercially manufactures, uses,
11 sells, offers to sell and/or imports any product that is the subject of ANDA No.
12 202818 that infringes the '561 patent;

13 21. A judgment declaring that infringement of the '561 patent is willful if
14 Watson commercially manufactures, uses, sells, offers to sell and/or imports any
15 product that is the subject of ANDA No. 202818 that infringes the '561 patent;

16 22. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an
17 exceptional case and awarding Shire its attorneys' fees and costs;

18 23. Such other and further relief as this Court may deem just and proper.

19 DATED: July 6, 2011

20 HENNIGAN DORMAN LLP
21 FROMMER LAWRENCE & HAUG LLP

22 By: 
23 Mieke K. Malmberg

24 Attorneys for Plaintiffs SHIRE LLC and
25 SHIRE DEVELOPMENT INC.
26
27
28

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge A. Howard Matz and the assigned discovery Magistrate Judge is David T. Bristow.

The case number on all documents filed with the Court should read as follows:

CV11- 5565 AHM (DTBx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

=====

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

☒ **Western Division**
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

☐ **Southern Division**
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

☐ **Eastern Division**
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.

COPY
AO 440 (Rev. 8/01) Summons in a Civil Action

UNITED STATES DISTRICT COURT

Central District of California

and
SHIRE LLC, SHIRE DEVELOPMENT INC.,

SUMMONS IN A CIVIL CASE

V.
WATSON LABORATORIES, INC.,

CV 11 - 05585
CASE NUMBER:

AHM

(DTBx)

TO: (Name and address of Defendant)
WATSON LABORATORIES, INC.
311 Bonnie Circle
Corona, California 92888

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Roderick G. Dorman (SBN 96908)
Mieke K. Malmberg (SBN 209992)
865 S. Figueroa Street, Suite 2900
Los Angeles, CA 90017
Tel: (213) 694-1200
Fax: (213) 694-1234

an answer to the complaint which is served on you with this summons, within twenty-one (21) days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

TERRY NAFISI

L. MURRAY

CLERK

DATE

JUL - 6 2011

(By) DEPUTY CLERK

RETURN OF SERVICE

Service of the Summons and complaint was made by me ⁽¹⁾	DATE
NAME OF SERVER (PRINT)	TITLE

Check one box below to indicate appropriate method of service

- ☐ Served personally upon the defendant. Place where _____
- ☐ Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.
Name of person with whom the summons and complaint were _____
- ☐ Returned _____
- ☐ Other (specify): _____

STATEMENT OF SERVICE FEES

TRAVEL	SERVICES	TOTAL
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DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on _____
Date

Signature of Server

Address of Server

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself <input type="checkbox"/>) SHIRE LLC SHIRE DEVELOPMENT INC.		DEFENDANTS WATSON LABORATORIES, INC.	
(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.) Roderick G. Dorman (SBN 96908) Mieke K. Malmberg (SBN 209992) Hennigan Dorman LLP 865 S. Figueroa Street, Suite 2900 Los Angeles, CA 90017 213-694-1200		Attorneys (If Known)	

II. BASIS OF JURISDICTION (Place an X in one box only.) <input type="checkbox"/> 1 U.S. Government Plaintiff <input type="checkbox"/> 2 U.S. Government Defendant <input checked="" type="checkbox"/> 3 Federal Question (U.S. Government Not a Party) <input type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)		III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only (Place an X in one box for plaintiff and one for defendant.) <table style="width:100%;"> <tr> <td style="width:50%;">Citizen of This State</td> <td style="width:10%;">PTF <input type="checkbox"/> 1</td> <td style="width:10%;">DEF <input type="checkbox"/> 1</td> <td style="width:30%;">Incorporated or Principal Place of Business in this State</td> <td style="width:10%;">PTF <input type="checkbox"/> 4</td> <td style="width:10%;">DEF <input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td>PTF <input type="checkbox"/> 2</td> <td>DEF <input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business in Another State</td> <td>PTF <input type="checkbox"/> 5</td> <td>DEF <input type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td>PTF <input type="checkbox"/> 3</td> <td>DEF <input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td>PTF <input type="checkbox"/> 6</td> <td>DEF <input type="checkbox"/> 6</td> </tr> </table>		Citizen of This State	PTF <input type="checkbox"/> 1	DEF <input type="checkbox"/> 1	Incorporated or Principal Place of Business in this State	PTF <input type="checkbox"/> 4	DEF <input type="checkbox"/> 4	Citizen of Another State	PTF <input type="checkbox"/> 2	DEF <input type="checkbox"/> 2	Incorporated and Principal Place of Business in Another State	PTF <input type="checkbox"/> 5	DEF <input type="checkbox"/> 5	Citizen or Subject of a Foreign Country	PTF <input type="checkbox"/> 3	DEF <input type="checkbox"/> 3	Foreign Nation	PTF <input type="checkbox"/> 6	DEF <input type="checkbox"/> 6
Citizen of This State	PTF <input type="checkbox"/> 1	DEF <input type="checkbox"/> 1	Incorporated or Principal Place of Business in this State	PTF <input type="checkbox"/> 4	DEF <input type="checkbox"/> 4																
Citizen of Another State	PTF <input type="checkbox"/> 2	DEF <input type="checkbox"/> 2	Incorporated and Principal Place of Business in Another State	PTF <input type="checkbox"/> 5	DEF <input type="checkbox"/> 5																
Citizen or Subject of a Foreign Country	PTF <input type="checkbox"/> 3	DEF <input type="checkbox"/> 3	Foreign Nation	PTF <input type="checkbox"/> 6	DEF <input type="checkbox"/> 6																

IV. ORIGIN (Place an X in one box only.) <input checked="" type="checkbox"/> 1 Original Proceeding <input type="checkbox"/> 2 Removed from State Court <input type="checkbox"/> 3 Remanded from Appellate Court <input type="checkbox"/> 4 Reinstated or Reopened <input type="checkbox"/> 5 Transferred from another district (specify): <input type="checkbox"/> 6 Multi-District Litigation <input type="checkbox"/> 7 Appeal to District Judge from Magistrate Judge					
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V. REQUESTED IN COMPLAINT: JURY DEMAND: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Check 'Yes' only if demanded in complaint.)		CLASS ACTION under F.R.C.P. 23: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		MONEY DEMANDED IN COMPLAINT: \$ TBD at trial	
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VI. CAUSE OF ACTION (Cite the U. S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.) 35 U.S.C §§1 et. seq. - patent infringement					
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VII. NATURE OF SUIT (Place an X in one box only.)					
OTHER STATUTES <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc. <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Act <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Info. Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes	CONTRACT <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loan (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	TORTS PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Fed. Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury-Med Malpractice <input type="checkbox"/> 365 Personal Injury-Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus-Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	TORTS PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability BANKRUPTCY <input type="checkbox"/> 22 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 American with Disabilities - Employment <input type="checkbox"/> 446 American with Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus/Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition FORFEITURE / PENALTY <input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 61 HIA(1395ff) <input type="checkbox"/> 862 Black Lung (923) 405(g) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS-Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number:

CV 11 - 05565AHM

(DTBX)

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☒ No ☐ Yes

If yes, list case number(s):

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☒ No ☐ Yes

If yes, list case number(s):

Civil cases are deemed related if a previously filed case and the present case:

- (Check all boxes that apply) ☐ A. Arise from the same or closely related transactions, happenings, or events; or
☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

- (a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.
☐ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*

California County outside of this District; State, if other than California; or Foreign Country

SHIRE LLC - Kentucky
 SHIRE DEVELOPMENT INC. - Pennsylvania

- (b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.
☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*

California County outside of this District; State, if other than California; or Foreign Country

WATSON LABORATORIES, INC. - County of Riverside

- (c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.
Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*

California County outside of this District; State, if other than California; or Foreign Country

All claims arose in the County of Riverside

* Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties

Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER):

Mie K. Malmberg

Date July 6, 2011

Mieke K. Malmberg

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3 -1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))